



Docket No.: 2869

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Christoph Hehrlein, et al.

Examiner: Thanh, Loan H.

Serial No.: 10/038,468

Art Unit: 3763

Filed: January 3, 2002

Title: DELIVERY SOURCE OF OXYGEN

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Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

BRIEF ON APPEAL

This appeal is taken from a rejection of the claims of the hereinabove referenced Patent Application in a final Office Action mailed October 12, 2006; oral hearing is waived.

REAL PARTY OF INTEREST

The present application is presently assigned to Christoph Hehrlein as evidenced by an assignment recorded February 15, 2002 on reel 013611, frame 0566.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences on applications related to the present application.

STATUS OF CLAIMS

<u>Appealed Claims (Claims Appendix)</u>	<u>Status</u>
29-30, 33-34 (all previously presented)	Rejected under 35 U.S.C. 102(b) on the basis of Grady patent US 5,084,011.
29-34 (all previously presented)	Rejected under 35 U.S.C. 103(a) on the basis of Rowe US 6,146,358 and Paradis US 5,334,142.

The status of claims 29-34 is appealed.

STATUS OF AMENDMENTS

No amendment has been made after the final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention as set forth in independent claim 29 provides for a substrate (1 Figure 1) (5, Figure 2) along with an elutable oxygenated fluorocarbon solution incorporated into the substrate 1, 5 and means (such as a membrane 7) for modulation release kinetics of the oxygenated fluorocarbon solution from the substrate.

The method as set forth in independent claim for the treatment of cardiovascular conditions, and includes oxygenating blood and/or tissue with a medical device which includes an oxygenated fluorocarbon solution and modulating release kinetics of the oxygenated fluorocarbon solution by changing a temperature of the device.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

ANTICIPATION

The Examiner has rejected claims 29-30 and 33-34 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,084,011 to Grady.

OBVIOUSNESS

The Examiner has rejected claims 29-34 under 35 USC 103(a) as being obvious over to U.S. Patent No. 6,146,358 to Rowe in view of U.S. Patent No. 5,334,142 to Paradis.

GROUPING OF CONTESTED CLAIMS

The Appellant specifically requests separate consideration and review of Group I claims which include claims 29-32, and Group II claims which includes claims 33-34. Specific consideration of the two groups is requested because of Group I claims are directed to apparatus and Group II claims are directed to a method.

ARGUMENT – ANTICIPATION – GROUP I CLAIMS

In the rejection of claims 29-30 and 33-34 under 35 USC 102(b) on the basis of Grady, the Examiner has stated that Grady teaches a method comprising the steps of oxygenation blood or tissue with a catheter which includes an oxygenated fluorocarbon solution and change in the temperature of the solution to a temperature between about 0 and 4° Celsius by the refrigeration unit 60 and exposing the device to that fluid. The Examiner has also stated that the substrate is considered to be the catheter, syringe, or cannula, a means for modulating can be interpreted as the lumen wall of the catheter or the refrigeration unit, and the means for exposing is considered to be the lumen wall of the tubular element.

It is by now well settled that the burden of establishing a *prima facie* case of anticipation resides with the patent and trademark office. *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984) quoting *In re Warner*, 154 USPQ 173 (CCPA 1967).

Anticipation under 35 USC 102 is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc., 221 USPQ 385 (Fed. Cir. 1984).

Inherency, however, may not be established by appearances, probabilities, or possibilities. The mere fact that a certain thing may result from given set of circumstances is not sufficient. *In re Oelrich*, 212 USPQ 323 (CCPA 1981).

The initial burden is on the Examiner to establish a reasonable basis for concluding that the characteristic in question will inherently occur. *In re Ludtke*, 169 USPQ 563 (CCPA 1971) and *In re Swinehart*, 169 USPQ 226 (CCPA 1971).

The Appellants submit that this initial burden has not been met.

With this criteria in mind, the Appellants submit that the Grady reference is totally silent with regard to the presence of an elutable oxygenated fluorocarbon solution which is incorporated into a substrate.

A thorough reading of Grady reveals that the only mention of "fluorocarbon" is in relation to the prior art reporting an infant breathing fluorocarbon liquid which was oxygenated with pure oxygen. See column 2, lines 40-51 of Grady.

Accordingly, there is no teaching of an elutable oxygenated fluorocarbon solution incorporated into a substrate.

With regards to means for modulating release kinetics of the oxygenated fluorocarbon solution from this substrate as set forth in independent claim 29, the only teaching in Grady is the use of a decreased temperature to maximally dissolve gaseous oxygen into liquids. See the abstract and column 3, beginning at line 13 under the summary of the invention. The refrigeration unit 60 can be activated to decrease the temperature of the gas and liquid solution to approximately 4° Centigrade in order to increase the solubility of oxygen. See column 6, lines 31-54.

Accordingly, the Grady reference teaches opposite that to the structure and function of the present invention which provides for means for modulating release kinetics of the oxygenated fluorocarbon solution from the substrate rather than utilizing temperature to maximally dissolve the gaseous oxygen into liquids.

Thus, in view of the lack of teaching of structure, similar to that claimed which functions in a manner resulting in the modulation of release kinetics of oxygenated fluorocarbon solution, a rejection under 35 USC 102(b) is not sustainable and the Board is respectfully requested to reverse the Examiner's the rejection of claims 29-32 under 35 USC 102(b) on the basis of the Grady reference.

ARGUMENT – ANTICIPATION – GROUP II CLAIMS

The hereinabove presented arguments with regard to traverse the Examiner's rejection of Group I claims are reiterated here.

In addition, Group II claims provide for oxygenating blood and/or tissue with a medical device which includes an oxygenated fluorocarbon solution. In view of the fact that Grady is totally silent with regard to a medical device which includes an oxygenated fluorocarbon solution, as hereinabove noted, of oxygenating blood and/or tissue with a medical device which includes an oxygenated fluorocarbon solution and modulating the release kinetics of the oxygenated

fluorocarbon solution by changing a temperature of the device.

Accordingly, the Appellant specifically requests the reversal of the rejection of Group II claims under 35 USC 102(a) on the basis of the Grady reference.

ARGUMENT – OBVIOUSNESS – GROUP I CLAIMS

The Examiner has rejected claims 29-32 under 35 USC 103(a) as being unpatentable over U.S. 6,146,358 to Rowe in view of U.S. 5,334,142 to Paradis.

In this rejection, the Examiner states that Rowe teaches a balloon having a substrate/control release carrier on the surface which incorporates a therapeutic agent to be delivered to the internal tissue of the patient.

The Examiner states that the means for modulating and exposing is considered to be within the inflation lumen of the catheter or wall or reservoir. As best understood by the Examiner the means of Rowe is able to perform the function of the means that the Appellant has claimed. That is, the Examiner has stated that the structure allows fluid to come into contact with the substrate coating/wall which is to be considered equivalent to the structure to the balloon catheter of the Appellant. The Examiner also has stated that it is well known that the temperature at which to deliver into a patient would be one of the bodies temperature which are between 0° and 50° Celsius.

The Examiner recognizes that Rowe is silent to the therapeutic agent to be an elutable oxygenated fluorocarbon solution. Therefore, the Examiner looks to Paradis for a disclosure of the delivery of oxygen carrying fluid (fluorocarbon) for infusion. The Examiner further states that Paradis discloses that any agent that is demonstrated as effective when administrated intravenously may be more effective when administered to the heart by the balloon catheter. The Examiner then concludes it would have been obvious to one of ordinary skill in the art at the time the invention

was made to substitute the therapeutic agent of Rowe with the oxygenated fluorocarbon solution as disclosed by Paradis as a substitution of different therapeutic agents for treatment with a balloon catheter.

The Appellants submit that the Examiner has not made out a *prima facie* case of obviousness under 35 USC 103.

In accordance with the CCPA in *In re Lintner*, 173 USPQ 560, 562, the court stated: "In determining the propriety of the Office Action case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient to one of ordinary skill in the relevant art having the references before him to make the proposed substitution, notion or other modification.".

As broadly stated, the criteria for finding obviousness under 35 USC 103 goes to the sufficiency of the reference teachings to justify the conclusion that the proposed modification is a reasonable and logical reconstruction of what a person having ordinary skill in the art would have found obvious to do at the time the invention was made. The court has held in *In re Regel*, Buchel, and Plempel, 188 USPQ 136 (CCPA 1975) that there must be some logical reason apparent from positive, concrete evidence of record would justify as a combination of primary and secondary references.

The Appellants would like to point out that the references relied on by the Examiner, namely Rowe and Paradis are totally silent as to teaching of an elutable oxygenated fluorocarbon solution incorporated into a substance and further means for modulating the release kinetics of the oxygenated fluorocarbon solution from the substrate through the use of temperature.

Apparently, the Examiner recognizes that the references are totally silent with regard to temperature and therefore concludes that it is well known that the temperature at which to deliver into a patient would be one of the body's temperature which is between 0° and 50° Celsius.

While this may be true, the Examiner has provided no factual support.

Without factual support, the Examiner's statement must be considered in the Examiner's opinion.

However, it has been established that factually unsupported opinions of the Examiner do not provide the factual basis required by the Supreme Court in *Graham v. John Deere* (148 USPQ 459, 1966) for the determination of obviousness under Section 103 (*In re Wagner and Folkers*, 152 USPQ 552 (CCPA 1967)).

Nonetheless, merely introducing something into the body at body temperature does not provide support for a suggestion or teaching of a means for modulating the release kinetics of oxygenated fluorocarbon solution from a substrate as presently claimed. There is simply no teaching in the references cited by the Examiner for modulating release kinetics of oxygenated fluorocarbon solution from a substrate.

Accordingly, the Appellants submit that the Examiner has not made a *prima facie* case of obviousness and respectfully requests the Board to reverse the rejection of claims 29-32 under 35 USC 103(a) on the basis of the Rowe and Paradis references.

ARGUMENT –OBFUSCATION – GROUP II CLAIMS

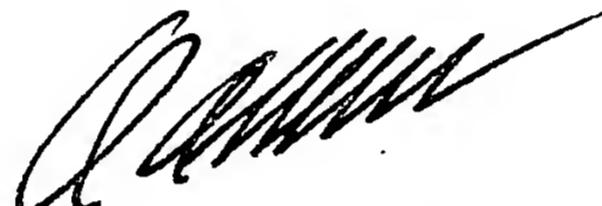
The hereinabove arguments presented in traverse of the Group I claims under 35 USC 103(a) are reiterated herewith.

Both Rowe and Paradis are totally silent with regard to any method utilizing an oxygenated fluorocarbon solution. The Appellants submit that with this lack of teaching by the references, the Examiner has not made a *prima facie* case of obviousness under 35 USC 103(a) on the basis of the Rowe and Paradis references.

Again, the Appellants specifically requests the Board to reverse the Examiner's rejection of Group II claims under 35 USC 103(a) on the basis of the Rowe and Paradis patents.

In view of the arguments hereinabove set forth, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reversal of the Examiner's decision is respectfully requested.

Respectfully submitted,



Walter A. Hackler, Reg. No. 27,792

Attorney of Record

2372 S.E. Bristol, Suite B

Newport Beach, California 92660

Tel: (949) 851-5010

Fax: (949) 752-1925

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WALTER A. HACKLER
REG. NO. 27,792

CLAIMS APPENDIX

Claims 1-28 cancelled.

29. (Previously Presented) A vascular device comprising:
 - a substrate;
 - an elutable oxygenated fluorocarbon solution incorporated in the substrate; and
 - means for modulating release kinetics of the oxygenated fluorocarbon solution from the substrate.
30. (Previously Presented) The device according to claim 29 wherein the means for modulating release kinetics of oxygenated fluorocarbon solution comprises means for exposing the substrate to a fluid having a temperature of between about 0°C and about 50°C.
31. (Previously Presented) The device according to claim 30 wherein the substrate comprises a membrane incorporated into at least one structure selected from a group consisting of a tube, a balloon, a perfusion balloon, a stent, and a wire.
32. (Previously Presented) The device according to claim 31 wherein the substrate comprises an inflatable balloon and the means for modulating release kinetics of oxygenated fluorocarbon solution comprises a fluid lumen through the balloon enabling fluid injection with temperature of between about 0°C and about 50°C for modifying the release kinetics.
33. (Previously Presented) A method for the treatment of cardiovascular conditions, the method comprising:
 - oxygenating blood and/or tissue with a medical device which includes an oxygenated fluorocarbon solution; and
 - modulating release kinetics of the oxygenated fluorocarbon solution by changing a temperature of the device.

34. (Previously Presented) The method according to claim 33 wherein modulating release of oxygenated fluorocarbon solution comprises exposing the device to a fluid having a temperature of between about 0°C and about 50°C.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE